DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2015

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Tang Hao
Product Approval Engineer
Mindray Building, Keji 12th Rd. South
Hi-tech Industrial Park
Nanshan
Shenzhen Guangdong
China 518057

Re: K150167
Trade/Device Name: V60 Anesthetic Vaporizer
Regulation Number: 21 CFR 868.5880
Regulation Name: Anesthetic Vaporizer
Regulatory Class: Class II
Product Code: CAD
Dated: May 22, 2015
Received: June 1, 2015

Dear Mr. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150167

Device Name
V60 Anesthetic Vaporizer

Indications for Use *(Describe)*
V60 Anesthetic Vaporizer is an unheated, calibrated anesthetic vaporizer used for evaporating liquid anesthetic agents and delivering mixed gas of controlled concentration to an anesthetic delivery system.

The V60 Anesthetic Vaporizer is available in models specific for use with Isoflurane and models available specific for use with Sevoflurane.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the V60 Anesthetic Vaporizer is provided below.

1. Statement

This is a Traditional 510(k) report for V60 Anesthetic Vaporizer, this is a new device for this submission.

2. Applicant Device Information

Device Proprietary Name:	V60 Anesthetic Vaporizer
Device Common Name:	Vaporizer, Anesthesia, non-heated
Classification Panel:	Anesthesiology
Classification Regulation:	Class II
Product Code:	CAD
Regulation Number:	868.5880

Indications for Use:

V60 Anesthetic Vaporizer is an unheated, calibrated anesthetic vaporizer used for evaporating liquid anesthetic agents and delivering mixed gas of controlled concentration to an anesthetic delivery system.

The V60 Anesthetic Vaporizer is available in models specific for use with Isoflurane and models available specific for use with Sevoflurane.

3. Submitter Information

Manufacturer Name:

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

Mindray Building, Keji 12th Road South

High-tech Industrial Park, Nanshan

Shenzhen 518057, P.R. China

Contact Person of the Submission:

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4. Legally Marketed Predicate Devices

Device Name: DRAGER-VAPOR 2000

K-number: K971923

Product Code: CAD

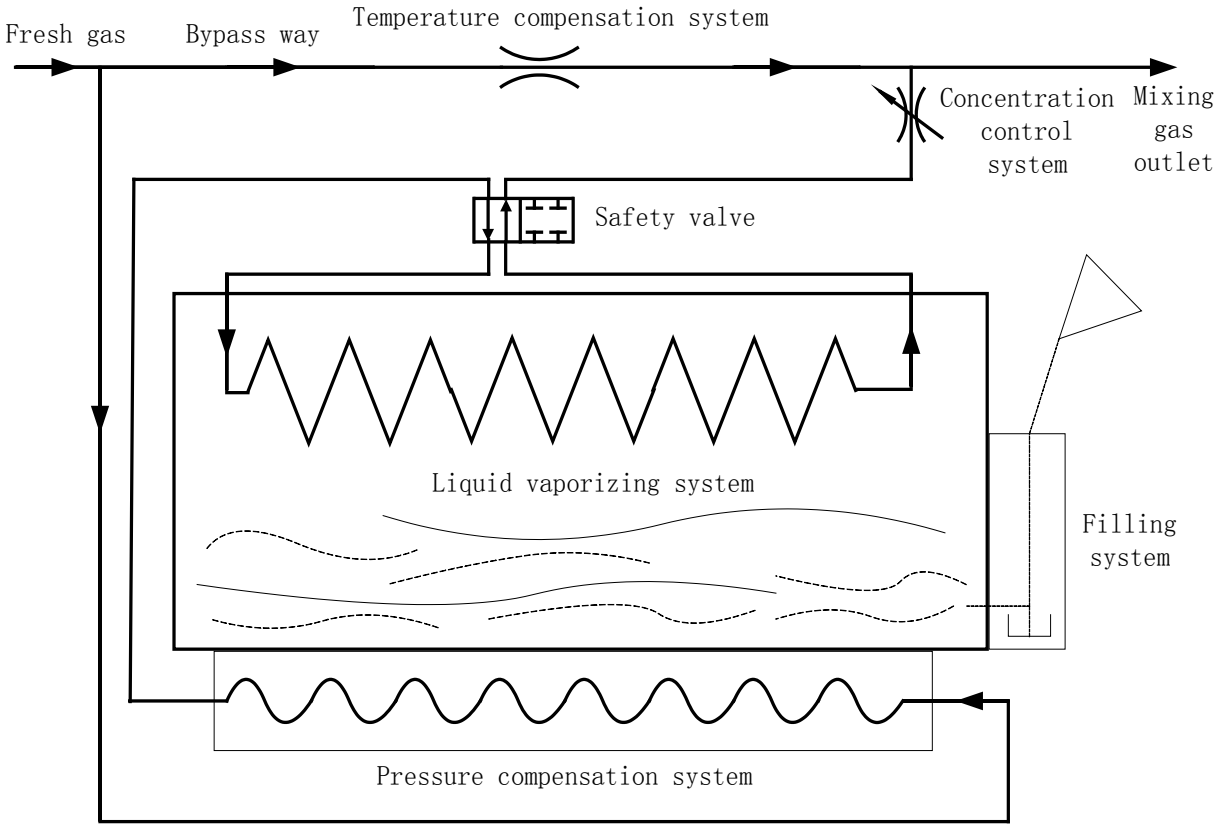
Intended Use: The Vapor 2000 is intended for vaporization and delivery of a controlled amount of liquid anesthetic agent. The Vapor 2000 is designed and labeled accordingly for use with Enflurane, Isoflurane, Halothane, and Sevoflurane.

Manufacturer: DRAGER MEDICAL, INC.

5. Device description:

Summary of Technological Characteristics:

The below figure illustrates the main internal functions of the Mindray V60 anesthetic vaporizer. Fresh gas enters the vaporizer and is then divided into two pathways. One pathway of fresh gas is called carrier gas which goes through the pressure compensation system and liquid vaporizing system. The other pathway of fresh gas is called diluted gas which goes through the bypass system and temperature compensation system. The two gas pathways of diluted gas and carrier gas then mix to form mixed anesthetic gas with a certain concentration before the outlet of the vaporizer.



- **Technological Comparison between predicate and proposed devices:**

  The subject Mindray V60 Anesthetic Vaporizer are substantially equivalent to predicate Drager vapor 2000 (K971923)vaporizers respecting indications for use, basic operation and performance specifications when used in non-MRI operating room

  The subject Mindray V60 Anesthetic Vaporizer and predicate Drager vapor 2000 share the same intended use

  To achieve intended use a vaporizer must
  1) Provide a filling system for the operator to fill anesthetic agent
  2) Be able to be installed correctly on an anesthetic delivery system
  3) Provide a mechanism to evaporate liquid anesthetic agents and deliver mixed gas of controlled concentration to an anesthetic delivery system
  4) Provide a mechanism for the user to adjust output concentration of agent

  As a result, to achieve the same intended use the subject Mindray V60 Anesthetic Vaporizer and predicate Drager vapor 2000 is substantially equivalent with respect to the above 4 items, that is
  1) Provide equivalent filling systems
  2) Share the same installation method and connector
  3) Share similar basic principle to output controlled concentration
  4) Provide equivalent mechanism to adjust output concentration

The following table illustrates the comparison of above mentioned key performance items between V60 vaporizer and predicate Drager vapor 2000 vaporizer (K971923)

<table>
<tr><th>Technical Characteristics</th><th>Proposed Device
Mindray V60 Anesthetic Vaporizer</th><th>Predicate Device
Drager Vapor 2000 Vaporizer (K971923)</th><th>Conclusion</th></tr>
<tr><td rowspan="3">Filling system</td><td>Pour Fill</td><td>Vapor of filling spout</td><td rowspan="3">Identical</td></tr>
<tr><td>Key Filler</td><td>Keyed filling</td></tr>
<tr><td>Quik-Fil</td><td>Quik Fil</td></tr>
<tr><td>Volume</td><td>360 ml (dry wick)
300 ml (moist wick)
260 ml (between the minimum and maximum marks)</td><td>360 ml (dry wick)
300 ml (moist wick)
260 ml (between the minimum and maximum marks)</td><td>Identical</td></tr>
<tr><td>Connection to anesthesia gas machine</td><td>Selectatec-compatible plug-in connectors</td><td>Selectatec-compatible plug-in connectors</td><td>Identical</td></tr>
<tr><td>Output concentration accuracy</td><td>
<table>
<tr><th>Operating environment</th><th>15 to 35℃ or 0.2 to 10 L/min</th><th>10 to 15℃ or 35 to 40℃ or 10 to 15 L/min</th></tr>
<tr><td>Set concentration ≤6%</td><td>±0.20 vol.% or ±20% rel., whichever is greater</td><td>+0.30/-0.20 vol.% or +25/-20% rel., whichever is greater</td></tr>
<tr><td>Set concentration > 6%</td><td>±0.25 vol.% or ±20% rel., whichever is greater</td><td>+0.35/-0.25 vol.% or +30/-20% rel., whichever is greater</td></tr>
</table>
</td><td>
<table>
<tr><th>Operating environment</th><th>15 to 35℃ or 0.25 to 10 L/min</th><th>10 to 15℃ or 35 to 40℃ or 10 to 15 L/min</th></tr>
<tr><td>Set concentration ≤6%</td><td>±0.20 vol.% or ±20% rel., whichever is greater</td><td>+0.30/-0.20 vol.% or +25/-20% rel., whichever is greater</td></tr>
<tr><td>Set concentration > 6%</td><td>±0.25 vol.% or ±20% rel., whichever is greater</td><td>+0.35/-0.25 vol.% or +30/-20% rel., whichever is greater</td></tr>
</table>
</td><td>Similar</td></tr>
</table>

Technical Characteristics	Proposed Device Mindray V60 Anesthetic Vaporizer	Predicate Device Drager Vapor 2000 Vaporizer (K971923)	Conclusion
Flow range	0.2 to 15L/min 0.2 to 10L/min for concentrations >5Vol.%	0.25 to 15L/min 0.25 to 10L/min for concentrations >5Vol.%	Similar
Maximum angle of tilt (fixed on machine)	30º	30º	Identical
Environmental conditions	Temperature 10 to 40℃ Humidity15 to 95%, non-condensing Atmospheric pressure 70 to 106 kPa	Temperature 10 to 40℃ Humidity 0 to 95%, non-condensing Atmospheric pressure 70 to 110 kPa	Similar
Difference between pressure range and ambient pressure on the vaporizer outlet	-10kPa~20kPa	-10kPa~20kPa	Identical
Resistance	70cmH2O@10L/min	70cmH2O@10L/min	Identical
Dial/calibration markings	Isoflurane Vaporizer 0、0.2、0.4、0.6、0.8、1.0、 1.5、2.0、2.5、3.0、3.5、4.0、5.0、6.0	Isoflurane Vaporizer 0、0.2、0.4、0.6、0.8、1.0、 1.5、2.0、2.5、3.0、3.5、4.0、5.0、6.0	Identical
	Sevoflurane Vaporizer 0、0.2、0.4、0.6、0.8、1.0、1.5、2.02.5、3.0、3.5、4.0、5.0、6.0、7.0、8.0	Sevoflurane Vaporizer 0、0.2、0.4、0.6、0.8、1.0、1.5、2.02.5、3.0、3.5、4.0、5.0、6.0、7.0、8.0	

Based on the above information it is concluded that the V60 Anesthetic Vaporizer is substantially equivalent to the above named predicate devices.

6. Substantial Equivalence Considerations

The V60 Anesthetic Vaporizer has been tested and found to be in compliance with FDA recognized performance standards.

The Biological Evaluation Tests are in compliance with the standards of ISO 10993, **"**Biological evaluation of medical devices". The compatibility of the gas contacting component materials in the finished product meets the requirement of Biocompatibility.

The applicant device is compliance with the standard of ANSI/AAMI ES60601-1:2005, and the product is safe during the use. It can be used in the clinical environment. It is substantially equivalent to other anesthetic vaporizer product.

A risk analysis has been developed to identify potential hazards and documents the mitigation of the hazards.

The V60 Anesthetic Vaporizer has been evaluated and found to meet its intended use and meet the user's specific needs.

The V60 Anesthetic Vaporizer has been tested and found to be in compliance with the following performance standards:

- **ISO 14971:2007,** Medical devices - application of risk management to medical devices.
- **ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A 2:2010/(R) 2012 (Consolidated Text)** Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC60601-1:2005, mod).
- **IEC 62366:2014,** Medical devices - application of usability engineering to medical devices.
- **ISO 10993-1: 2009,** Biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process.
- **ISO 10993-5: 2009,** Biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity.
- **ISO 10993-10: 2010,** Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization.
- **ISO 15223-1:2012,** Medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements.

- **IEC 60601-2-13:2009,** Medical electrical equipment - part 2-13: particular requirements for the safety and essential performance of anaesthetic systems.
- **ISO 5360:2012,** Anaesthetic vaporizers - agent specific filling systems.
- **ISO 8835-4:2004,** Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices.
- **IEC 60601-1-6:2010,** medical electrical equipment -- part 1-6: general requirements for basic safety and essential performance -- collateral standard: usability.

However, the V60 Anesthetic Vaporizer often has gas path materials which cannot be tested by the above listed tests. We performed a number of non-clinical tests to demonstrate the biocompatibility of the V60 Anesthetic Vaporizer.

These tests included:

- Particulates Matter testing ($PM_{2.5}$/PM_{10})
- Volatile Organic Compounds testing (VOCs)

We performed as intended in each test. These tests results indicated that the V60 Anesthetic Vaporizer complies with its predetermined specifications and FDA recognized consensus standards. These tests were equivalent to the testing required of the predicate devices.

7. Performance Data

- To establish the substantial equivalence of the V60 Anesthetic Vaporizer, Mindray conducted functional and system level testing on the subject devices. The testing provided an evaluation of the performance of each of the models of the subject device. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

- The following table is a summary of performance testing that has been conducted on the subject V60. Testing was designed in accordance with industry-recognized methods. All performance of the V60 vaporizer was verified through the successful completion of all tests.

Tests	Description	Test report Index
Filling Rate	Record the time needed to fill certain volume of agent and then calculate the filling rate	Appendix H4 (minima and maxima as per clauses 8 of ISO 5360)
Filling Leakage	Weigh the vaporizer and agent bottle before and after filling to calculate the filling leakage	Appendix H4 (minima and maxima as per clauses 9 of ISO 5360)
Volume	Measure the volume needed to fill the vaporizer	Appendix H10, Chapter 4.16
Output Concentration Accuracy	Verify that the output concentration of V60 vaporizers can meet the product specifications when the vaporizer working at specified conditions	Appendix H10, Chapters 4.12, 4.14
Flow Rates	Verify that the output concentration of V60 vaporizers can meet the product specifications with specified flow rate	Appendix H10, Chapter 4.14
Maximum Angles of Tilt	Verify that the output concentration of V60 vaporizers can meet the product specifications with specified maximum tilt angle	Appendix H10, Chapter 4.17; Appendix G1
Temperature Range	Verify that the output concentration of V60 vaporizers can meet the product specifications with specified temperature	Appendix H10, Chapter 4.12; Appendix G3
Humidity, Maximum Atmospheric Pressure	Verify that the output concentration of V60 vaporizers can meet the product specifications with specified humidity and atmospheric pressure	Appendix G3
Difference Between Pressure Range & Atmospheric Pressure at Outlet	Verify that the output concentration of V60 vaporizers can meet the product specifications with specified back pressure at outlet	Appendix H10, Chapter 4.13
Resistance	Measure the pressure rise at inlet of the V60 vaporizers when the vaporizer is routed with 10L/min gas flow	Appendix H10, Chapter 4.18

Dial Mark Calibration	Inspect Dial Mark Calibration on control dial of the V60 vaporizers	Appendix H10, Chapter 4.7
Compatibility testing	Verify that the V60 vaporizers are compatible with anesthesia machine with Selectatec manifold including installation , leakage and interlock function	Appendix H10, Chapter 4.6, 4.9, 4.19

8. Substantial Equivalence Conclusion

The applicant device has demonstrated through performance testing, same classification information, same performance, same indications and intended use, same design principle and feature, similar product design and specifications, and non-clinical testing that the proposed devices and predicate have been found to be substantially equivalent.